Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for external lower extremity nerve stimulators for Restless Legs Syndrome. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 882.5887 to subpart F to read as follows:

§ 882.5887 External lower extremity nerve stimulator for Restless Legs Syndrome.

(a) *Identification.* An external lower extremity nerve stimulator for Restless Legs Syndrome is a prescription device that uses external electrical stimulators and cutaneous electrodes to stimulate nerves in the lower extremity (*e.g.,* peroneal nerves) and evoke tonic, sustained muscle activation in the legs to reduce the symptoms of Restless Legs Syndrome.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must include:

(i) Characterization of the electrical stimulation parameters, including the following: waveforms; output modes; maximum output voltage and maximum output current (at 500Ω, 2kΩ, and 10kΩ loads); pulse duration; frequency; net charge per pulse; and maximum phase charge, maximum current density, maximum average current, and maximum average power density (at 500Ω);

(ii) Characterization of the therapy output across sudden and rapid changes in load impedance; and

(iii) Characterization of electrode performance, including electrical performance, adhesive integrity, shelf life, reusability, and variation of impedance over the use of therapy.

(2) The tissue-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance testing must demonstrate electrical, thermal, and mechanical safety along with electromagnetic compatibility of the device in the intended use environment.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Physician and patient labeling must include the following:

(i) Recommended treatment regimens, including frequency and duration of use, and identification of application site(s);

(ii) Typical sensations experienced during treatment;

(iii) Methods for identifying the appropriate stimulation intensity that is needed to reduce symptoms of Restless Legs Syndrome and is tolerable to patients;

(iv) A shelf life for the electrode and reuse information;

(v) Summaries of the electrical stimulation parameters and device technical parameters (including any wireless specifications); and

(vi) Instructions on how to maintain the device, including all user-interface components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12904 Filed 6–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2026–N–6730]

Medical Devices; Neurological Devices; Classification of the Computerized Behavioral Therapy Device for the Treatment of Fibromyalgia Symptoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the computerized behavioral therapy device for the treatment of fibromyalgia symptoms into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the computerized behavioral therapy device for the treatment of fibromyalgia symptoms. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 26, 2026. The classification was applicable on May 9, 2023.

FOR FURTHER INFORMATION CONTACT: Amber Ballard, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4226, Silver Spring, MD 20993–0002, 204–402–9983, *Amber.Ballard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the computerized behavioral therapy device for the

treatment of fibromyalgia symptoms into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On November 21, 2022, FDA received Swing Therapeutics, Inc.'s request for De Novo classification of the Stanza device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 9, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 882.5804.[1] We have named the generic type of device ''computerized behavioral therapy device for the treatment of fibromyalgia symptoms,'' and it is identified as a prescription device intended to provide a computerized version of behavioral therapy for the treatment of fibromyalgia symptoms.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR COMPUTERIZED BEHAVIORAL THERAPY DEVICES FOR THE TREATMENT OF FIBROMYALGIA SYMPTOMS

Identified risks to health	Mitigation measures
Worsening of condition due to device providing ineffective treatment	Clinical data; and Labeling.
Delayed access to treatment due to device software failure	Software verification, validation, and hazard analysis.
Ineffective treatment due to use error/improper use of device	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, computerized behavioral therapy devices for the treatment of fibromyalgia symptoms are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for computerized behavioral therapy devices for the treatment of fibromyalgia symptoms. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 882.5804 to subpart F to read as follows:

§ 882.5804 Computerized behavioral therapy device for the treatment of fibromyalgia symptoms.

(a) *Identification.* A computerized behavioral therapy device for the treatment of fibromyalgia symptoms is a prescription device intended to provide a computerized version of behavioral therapy for the treatment of fibromyalgia symptoms.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must demonstrate that the device performs as intended under the anticipated conditions of use and include the following:

(i) Evaluation of improvement in the symptoms of fibromyalgia; and

(ii) Evaluation of relevant adverse events.

(2) Software verification, validation, and hazard analysis must demonstrate that the device performs as intended.

(3) Physician and patient labeling must include the following:

(i) Recommended treatment regimes, including frequency and duration of use; and

(ii) A summary of the clinical data for the device, including a discussion of adverse events.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12901 Filed 6–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2026–0479]

Southern California Annual Firework Events for the Los Angeles Long Beach Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce safety zones for annually reoccurring fireworks events taking place on July 4, 2026 in the Los Angeles—Long Beach Captain of the Port Zone. This action is necessary and intended to provide for the safety of life and property on the navigable waterways during these events. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any official patrol vessel.

DATES: The regulations in 33 CFR 165.1125 will be enforced on July 4, 2026 for the safety zones identified in the **SUPPLEMENTARY INFORMATION** section below for the times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Commander Kevin Kinsella, U.S. Coast Guard Sector Los Angeles—Long Beach at telephone (310) 467–2099 or email *D11-SMB-SectorLALB-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones in 33 CFR 165.1125 for the below listed events under Table 1 of § 165.1125, for the 2026 Fourth of July Fireworks Displays.

Item #2: LA County Dept of Beach and Harbors 4th of July Fireworks

- *Location:* Main Ship Channel of Marina del Rey, CA.
- *Date:* July 4, 2026.
- *Time:* Safety Zone enforced from 8 p.m. to 10:30 p.m.

Item #3: Fourth of July Fireworks, City of Dana Point

- *Location:* Offshore Dana Point Harbor, CA.
- *Date:* July 4, 2026.
- *Time:* Safety Zone enforced from 9 p.m. to 10:30 p.m.

Item #6: Fourth of July Fireworks, Emerald Bay Community Association.

- *Location:* Offshore Laguna Beach, CA.
- *Date:* July 4, 2026.